

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 48 and 50-59 are pending.

Applicants' amendment and response filed March 9, 2009 are acknowledged.

Applicants' response has been fully considered. Claim 48 has been amended, and claim 49 has been cancelled. Thus, claims 48 and 50-59 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claims 50-59 is withdrawn in view of applicants' amendment to the claim, and applicants' cancellation of the claims in the amendment filed March 9, 2009.

### **Withdrawn Claim Rejections - 35 USC § 102**

3. The previous rejection of claims 48 and 49 under 35 U.S.C. 102(b) as being anticipated by Habener (U.S. Patent 5,120712) is withdrawn in view of applicant's amendment to the claim, applicants' cancellation of the claims, and applicant's response at page 4 of the amendment filed March 9, 2009.

### ***Examiner's Amendment***

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard W. Bork on April 1, 2009.

#### **Examiner's Amendment to the Specification:**

Please replace the paragraph amended at page 1 of the preliminary amendment filed January 30, 2001 with the following paragraph:

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation Of U.S. application no. 09/068,822 filed on May 14, 1998, now abandoned, which is a 371 national application of PCT/DK96/00106 filed on March 18, 1996, which claims priority to Danish application 275/95 filed March 17, 1995, the contents of which are fully incorporated herein by reference.

### **Examiner's Amendment to the Claims:**

Claim 53 has been amended as follows:

53. (Currently amended) The derivative of claim 52, wherein the spacer is Lys and the lipophilic substituent is -CO(CH<sub>2</sub>)<sub>m</sub>CH<sub>3</sub> wherein m is an integer from 8 10 to 18 and is attached to the ε-amino group of the spacer.

**The following is an Examiner's Statement of Reasons for Allowance:** The following references are related to the claimed invention. Habener (U.S. Patents 5,120712 ('712 patent) and 5,118,666 ('666 patent), published June 1992) teaches a GLP-1 derivative having a formula H<sub>2</sub>N-X-CO-R<sup>1</sup>, where X is the peptide comprising the sequence His-Ala-G1u-Gly-Thr-Phe-Thr-Ser-Asp-Va1-Ser-Ser-Tyr-Leu-G1u-G1y-Gln-A1a-Ala-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-Gly; R<sup>1</sup> is OH, OM or -NR<sup>2</sup>R<sup>3</sup>; M is a pharmaceutically acceptable cation or a lower (C<sub>1</sub>-C<sub>6</sub>) branched or unbranched alkyl group; and R<sup>2</sup> and R<sup>3</sup> are each hydrogen or a lower (C<sub>1</sub>-C<sub>6</sub>) branched or unbranched alkyl group. Danley *et al.* (EP 0619322 B1, published 1994) indicate the derivatives of GLP-1(7-37) disclosed in '666 and '712 patents include C-terminal salts, esters and amides where the salts and esters are defined as OM, where OM is a pharmaceutically acceptable cation or a lower (C<sub>1</sub>-C<sub>6</sub>) branched or unbranched alkyl group and the amides are defined as NR<sup>2</sup>R<sup>3</sup> where R<sup>2</sup> and R<sup>3</sup> are the same or different and are selected from the group consisting of hydrogen and a lower (C<sub>1</sub>-C<sub>6</sub>) branched or unbranched alkyl group. Therefore, the references do not teach or suggest a derivative of GLP-1 or an analog thereof where a lipophilic substituent having a straight chain of 12 to 35 carbon atoms and optionally having an amino group is optionally via a spacer attached to the C-terminal amino acid of GLP-1, where the spacer is Lys, Glu, Asp, Glu-Lys or Asp-Lys. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

April 1, 2009